SYNTHES®

MAY 0 2 2014

5 510(k) Summary

Date Prepared April 30, 2014

Submitter

Synthes (USA) Products LLC
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Contact

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Device Name MatrixRIB Plating System

Device Classification Information

Product Code	Device Name	Device Class	Regulation Number	Regulation Description
HRS	Plate, Fixation, Bone	2	21 CFR 888.3030	Single/multiple component metallic bone fixation appliances and accessories

The MatrixRIB Fixation System contains the above Class 2 implants and also includes Class 1 instruments and accessories.

Predicate Devices

- Synthes MatrixRIB Fixation System (K081623)
- Synthes Sternal Fixation System (K112689, K093772, K081700, K050041, K010943)
- MedXpert STRATOS (K073556)

Indications for Use

The MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone for the fixation, stabilization, and reconstruction of:

- fractures, fusions, osteotomies, and/or resections of the ribs and sternum, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

Device Description

The MatrixRIB Fixation System consists of locking plates, locking screws, and intramedullary splints for fixation and stabilization of the chestwall. These implants are available in multiple sizes and are manufactured from titanium alloy (Ti-6Al-7Nb).

Comparison to Predicate Devices

Indications
The predicate devices are indicated for use in chest wall of the skeleton (i.e. ribs and sternum) for a variety of surgical applications (rib fixation, chest wall reconstruction, and chest wall deformity repair). The Indications for Use statement of the MatrixRIB Fixation System presented in this submission is a superset of the indications statements of the predicate devices. The differences in the Indications statement for the proposed device in comparison to the predicates do not constitute a new intended use not already addressed by the predicates.

Technological Similarities of the MatrixRIB Plates
- Same principles of operation as the existing MatrixRIB and Synthes Sternal Fixation System predicates, i.e. metallic plates that can be fixated to bone.
- Similar sizes and shapes compared to the predicates.
- Proposed 24-hole and 30-hole straight plates have the same thickness and curved cross-section as the existing MatrixRIB universal plate.
- Proposed plates have the same locking screw hole design as the existing predicate MatrixRIB plate, and therefore are compatible with the existing MatrixRIB screws.
- Same material as the existing MatrixRIB plates.

Technological Differences of the MatrixRIB Plates
- MatrixRIB sternal plates (made from Titanium alloy) are thinner than the Synthes Sternal Fixation System predicate plates (made from commercially pure Titanium).
- Most plates in the predicate Synthes Sternal Fixation System have an emergency release pin; no MatrixRIB plates contain an emergency release pin.
- The STRATOS predicate employs rib clips and connecting bars for fixation/repair which are made from commercially pure Titanium; the MatrixRIB system employs plates and screws for fixation/repair which are made from Titanium alloy.

Technological Similarities of the MatrixRIB screws
- Same principles of operation – metallic implants for the fixation of bone.
- Similar lengths as the predicates.
- Same solid shaft as the existing MatrixRIB Fixation System predicate.
- Same thread pitch as the existing MatrixRIB Fixation System predicate.
- Same material as the predicates.

Technological Differences of the MatrixRIB screws
- The major diameter of the MatrixRIB screw is slightly smaller than the Synthes Sternal Fixation System predicates.

Non-clinical performance data

Non-clinical testing and analyses comparing the proposed devices to the predicates within this submission include:

- Dynamic compression bending of plates
- Cantilever bending of plates
- Torque testing and pull-out strength of screws

The non-clinical performance data demonstrate that the mechanical performance of the proposed MatrixRIB Fixation Systemis comparable to that of the predicates.

Clinical performance data

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence

The proposed deviceshave the same intended use as the predicate devices. The mechanical testing included in this submission demonstrates that:

- Any differences in technological characteristics of the predicates do not raise any new questions of safety and effectiveness.
- The proposed devicesare at least as safe and effective as the predicates.

It is concluded that the information included in this submission supports substantial equivalence.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

Synthes (USA) Products LLC
Mr. Damon Lees
Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K133616
Trade/Device Name: MatrixRIB Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 11, 2014
Received: April 14, 2014

Dear Mr. Lees:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

4 Indications for Use Statement

510(k) Number (if known): K133616 (pg 1/1)

Device Name:

MaxtrixRIB Fixation System

Indications for Use:

The MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone for the fixation, stabilization, and reconstruction of:

- fractures, fusions, osteotomies, and/or resections of the ribs and sternum, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

Contraindications:

The MatrixRIB Fixation System is contraindicated for:

- The fixation of the sternum in acute cardiac patients, due to the potential delay if emergent re-entry is required
- Screw attachment or fixation to the clavicle or spine
- Use in patients with latent or active infection, with sepsis, or who are unwilling or incapable of following postoperative care instructions

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tara N. Shepherd

Division of Orthopedic Devices